



04 JAN 2021

FDA CIRCULAR  
No. 2021-002

**TO: ALL MEDICAL DEVICE MANUFACTURERS, TRADERS, AND DISTRIBUTORS AND OTHER CONCERNED PARTIES**

**SUBJECT: Full Implementation of Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"**

## I. RATIONALE

On 26 January 2018, DOH Administrative Order (AO) No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" was issued to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the Common Submission Dossier Template based on the provisions of ASEAN Medical Device Directive (AMDD).

Section IX of the abovementioned AO stipulates that the requirement of registration for all medical devices not indicated in the list of registrable medical devices shall be implemented in phases and that the schedule of implementation shall be issued in separate memoranda.

The phases are listed as follows:

1. Phase 1: Notification of Class B (low-moderate risk), C (moderate-high risk) and D (high risk) that are non-registrable medical devices based on FDA Memorandum Circular (MC) No. 2014-005. FDA MC 2014-005 was superseded by the list of medical devices in Annex A of FDA Circular No. 2020-001 entitled "Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements"
2. Phase 2: Registration of Class D (Notification of Class D shall cease during this phase)
3. Phase 3: Registration of Class B and Class C (Notification of Class B and C shall cease during this phase)



To implement the three (3) phases and to provide for the schedule of the full implementation of AO 2018-0002, this Circular is hereby issued for compliance and guidance of all concerned.

## **II. OBJECTIVE**

This Circular aims to provide guidelines on the following:

1. Schedule of acceptance of applications for and issuance of Certificate of Medical Device Notification (CMDN) for Class B, C and D medical devices covered under Phase I implementation of AO 2018-0002
2. Submission of application for Certificate of Medical Device Registration (CMDR) for Class B, C and D covered under Phase 2 and Phase 3 implementation of AO 2018-0002

## **III. GUIDELINES**

1. The Center for Device Regulation, Radiation Health, and Research shall be accepting applications for CMDN for Class B, C and D medical devices that are not included in the list of medical devices in Annex A of FDA Circular No. 2020-001 and its subsequent amendment(s) upon the effectivity of this Circular.
2. The filing of application for CMDN for Class B, C and D medical devices shall follow the existing procedure for filing of application for CMDN for Class A medical devices.
3. The CMDN for Class B, C, and D medical devices shall be valid for two (2) years
4. Three (3) months prior to the expiration of the CMDN, the company shall apply for a CMDR for the product. Application for CMDR for Class B, C and D medical devices covered in this Circular shall follow the existing CMDR policies and procedures.
5. Classification of medical devices that are not included in Annex A of FDA Circular No. 2020-001 and its amendment(s) shall follow the classification rules of AMDD as stated in item 2, Section V. General Guidelines of AO 2018-0002.
6. The applicant shall submit the legal and technical requirements specified in Annex A and Annex B, respectively, of AO 2018-0002 when applying for CMDN for Class B, C and D medical devices covered in this Circular.
7. The fee for CMDN shall be ₱3,000.00 and an additional 1% thereof for the Legal Research Fee (LRF). This LRF imposition is pursuant to FDA Circular No. 2011-003 or the "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856".

8. The fee for the CMDR shall be in accordance with the existing fees during the time of the application.

**IV. PENALTY CLAUSE**

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations.

**V. SEPARABILITY CLAUSE**

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

**VI. EFFECTIVITY**

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register.

  
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Director General

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